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HOWREY LLP
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DRIVE, SUITE 200
FALLS CHURCH, VA 22042-7195

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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/356,322	SHALON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-19,21-27 and 29-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-19,21-27 and 29-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 14 September 2006 in which claims 7-9, 16, 21-23, 34 and 36 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 March 2006 under 35 U.S.C. 112, first and second paragraphs are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(e) are maintained as detailed below. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 7-19, 21-27, 29-40 are under prosecution.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, Parent Applications 08/514,875; 08/477,809; and 08/261,388 upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 14, 29, 35 and 38-39 of this application. Instant Claims 14 and 29 are drawn to "covalently bound DNA"; These elements are not supported by the parent application cited above. Therefore the effective filing date for Claims 14, 29, 35 and 38-39 is the filing date of Application No. 08/688,488 i.e. 30 July 1996.

Response to Arguments

3. Applicant's remarks regarding support for Claims 35 and 38-39 are found convincing. The effective filing date for Claims 35, 38 and 39 is the filing date of parent application 08/514,875 i.e. 14 August 1995.

However, Applicant's remarks and citations regarding support for covalently bound DNA is not found persuasive. The cited passage describes the surface of the support having charged groups e.g. polycationic polymer.

> In one general embodiment, the surface is a relatively hydrophilic, i.e., wettable surface, such as a surface having native, bound or

> covalently attached charged groups. One such surface described below is a glass surface having an absorbed layer of a polycationic polymer, such as poly-l-lysine.

The specification further describes the polymers having charged group, the polymer attachment to the support and subsequent deposition of polynucleotides whereby the polynucleotides are non-covalently bound (see ¶ spanning page 27-28 through first full paragraph of page 28 of 08/514,875).

> The slide is coated by placing a uniform-thickness film of a polycationic polymer, e.g., poly-l-lysine, on the surface of a slide and drying the film to form a dried coating. The amount of polycationic polymer added is sufficient to form at least a monolayer of polymers on the glass surface. The polymer film is bound to surface via electrostatic binding between negative silyl-OH groups on the surface and charged amine groups in the polymers. Poly-l-lysine coated glass slides may be obtained commercially, e.g., from Sigma Chemical Co. (St. Louis, Mo.).
> To form the microarray, defined volumes of distinct polynucleotides are deposited on the polymer-coated slide, as described in Section II. According to an important feature of the substrate, the deposited polynucleotides remain bound to the coated slide surface non-covalently when an aqueous DNA sample is applied to the substrate under conditions which allow hybridization of reporter-labeled polynucleotides in the sample to complementary-sequence (single-stranded) polynucleotides in the substrate array. The method is illustrated in Examples 1 and 2.

The '875 application does not teach or describe covalently bound DNA as asserted. The effective filing date for covalently bound embodiments is the filing date of Application No. 08/688,488 i.e. 30 July 1996.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States

> before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 7-19, 21-27, 29-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al (U.S. Patent No. 6,610,482 filed 6 December 1990).

Regarding Claim 7, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 1000 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length (Claims 40-43 & 56).

Regarding Claim 8, Fodor et al disclose the substrate wherein density is at least 10,000 regions/cm^2 (Claim 42).

Regarding Claim 9, Fodor et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm^2 (Claim 42).

Regarding Claim 10 Fodor et al disclose the substrate wherein the substrate is glass (Claim 61).

Regarding Claim 11 Fodor et al disclose the substrate wherein the substrate is non-porous i.e. glass (Claim 61).

Regarding Claim 12, Fodor et al disclose the substrate wherein the surface is hydrophobic e.g. plastics or hydrophobic linkers (Column 17, lines 14-48).

Regarding Claim 13, Fodor et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 17, lines 24-29).

Regarding Claim 14, Fodor et al disclose the substrate wherein the DNA sequences are covalently bound (Column 8, lines 21-27).

Regarding Claim 15, Fodor et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27).

Regarding Claim 16, Fodor et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27) and the surface has cationic polymer on the surface (Column 18, lines 3-8).

Regarding Claim 17, Fodor et al disclose the substrate wherein the sequences are genomic DNA sequences (e.g. Column 85, lines 25-37).

Regarding Claim 18, Fodor et al disclose the substrate has at least 2500 or more regions i.e. 10,000/cm^2 (Claim 42).

Regarding Claim 19, Fodor et al disclose the substrate has at least 10,000 regions (Claim 42).

Regarding Claim 21, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 100 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length (Claims 40-43 & 56). Fodor et al does not teach the method steps recited in the claim. However, the method steps do not result in any structural or compositional difference over the substrate of Fodor. Furthermore, the courts have stated that the process of making a product does not distinguish the product over the prior art.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 22, Fodor et al disclose the substrate wherein density is at least 10,000 regions/cm^2 (Claim 42).

Regarding Claim 23, Fodor et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm^2 (Claim 42)

Regarding Claim 24, Fodor et al disclose the substrate wherein the substrate is glass (Claim 61).

Regarding Claim 25, Fodor et al disclose the substrate wherein the substrate is non-porous i.e. glass (Claim 61).

Regarding Claim 26, Fodor et al disclose the substrate wherein the surface is hydrophobic e.g. plastics or hydrophobic linkers (Column 17, lines 14-48).

Regarding Claim 27, Fodor et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 17, lines 24-29).

Regarding Claim 29, Fodor et al disclose the substrate wherein the DNA sequences are covalently bound (Column 8, lines 21-27).

Regarding Claim 30, Fodor et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27).

Regarding Claim 31, Fodor et al disclose the substrate wherein the sequences are genomic DNA sequences (e.g. Column 85, lines 25-37).

Regarding Claim 32, Fodor et al disclose the substrate has at least 2500 or more regions i.e. 10,000/cm^2 (Claim 42).

Regarding Claim 33, Fodor et al disclose the substrate has at least 10,000 regions (Claim 42).

Regarding Claim 34, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 1000 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length and unique (i.e. different) in each region (Claims 40-43 & 56).

Regarding Claim 35, Fodor et al disclose the substrate of Claim 34. Fodor et al further teach the substrate is used for expression analysis (Column 66, lines 17-27). Fodor et al do not specifically teach detection of a two-fold change in abundance. However, the claimed detection is a recitation of intended use and the courts have stated that a recitation of intended

use not distinguish a device over the prior art. Therefore, the detection does not further define the substrate of Claim 34.

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claim 36, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 1000 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length and unique (i.e. different) in each region (Claims 40-43 & 56). Fodor et al further teach the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27) and the surface has cationic polymer on the surface (Column 18, lines 3-8).

Regarding Claim 37, Fodor et al disclose the substrate wherein the DNA microarray is used to detect mRNA (e.g. Column 66, lines 17-27). Hence, the substrate comprises DNA complementary to mRNA i.e. cDNA.

Regarding Claim 38, Fodor et al disclose the substrate wherein the DNA is used to detect distinct gene sequences (e.g. Column 117). Fodor et al further teach the gene sequences have expression levels different for control vs test e.g. alleles (Column 117, lines 20-49).

Regarding Claim 39, Fodor et al disclose the substrate wherein the DNA is used to detect distinct gene sequences (e.g. Column 117). Fodor et al further teach the gene sequences have expression levels different for control vs test e.g. alleles (Column 117, lines 20-49).

Regarding Claim 40, Fodor et al disclose the substrate wherein the regions are of a density between about 62,500 and 625 regions/cm^2 (e.g. 10^4 , 10^5 ,10^6 etc. regions, Column 21, lines 4-8).

Response to Arguments

6. Applicant asserts that the priority document (i.e. U.S. Patent No. 5,800,992) for the '482 patent does not provide support for the 50 or more subunits as instantly claimed. To support the assertion, Applicant points to a teaching in the '992 patent that describes probe length selection as being "determined to some extent by practical limits". Applicant cites a passage in the '992 patent that discusses construction of arrays comprising all possible probes of a defined length e.g. all 8-mers. The passage teaches that the number of probes encompassed by a complete n-mer increases as the length increases such that "Eventually the size of the matrix and the limitations in the resolution of regions in the matrix....becomes disadvantageous". Applicant asserts that this teaching indicates that a 50-mer would require an "astronomic number of probes".

The assertion is noted but not found convincing to overcome the above rejection. The passage cited by Applicant describes construction of an array having all possible probes of a defined length "n". The cited passage does not teach or suggest probes of 50 nt cannot be synthesized. The cited passage does not teach or suggest synthesis of 50-mers would be disadvantageous. The cited passage merely teaches special complications to be considered when constructing an array of all possible probes of a defined length. The instant claims are drawn to arrays of 1,000 probes of 50 nucleotides. The '992 patent teaches arrays of 50-mer probes (Column 20, lines 27-39 and Column 28, lines 40-43). Furthermore, the instant claims are not drawn to complete n-mer arrays, therefore any discussion of complete n-mers is not commensurate in scope with the claims.

Applicant asserts that "by the time of the filing of the application Serial No. 08/670,118, i.e., June 25, 1996, the Fodor group was working on VLSIPS technology, which could not have produced a microarray of polynucleotides each having more than 50 monmeric units." The assertion is noted. However, Applicant has not provided any factual evidence of

the asserted inability. Therefore, the assertion is deemed unsupported arguments of counsel. This is not to be considered an invitation for Applicant to submit a Declaration because a Declaration submitted after Final Action would not be deemed timely.

> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. (see MPEP 716.01).

It is further noted that the '992 patent is not limited to VLSIPS technology as asserted. The reference specifically teaches attachment of preformed probes onto the array surface (e.g. Column 27, lines 20-30).

7. Claims 7-15, 17-19, 21-27, 29-35, 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992).

Regarding Claim 7, Winkler et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length (Column 17, lines 49-57 and Column 18, lines 47-50).

Regarding Claim 8, Winkler et al disclose the substrate wherein density is at least 10,000 regions/cm^2 (Column 18, lines 47-50).

Regarding Claim 9, Winkler et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm^2 (Column 18, lines 47-50)

Regarding Claim 10 Winkler et al disclose the substrate wherein the substrate is glass (Column 14, lines 45-46).

Regarding Claim 11 Winkler et al disclose the substrate wherein the substrate is non-porous i.e. glass (Column 14, lines 45-46).

Regarding Claim 12, Winkler et al disclose the substrate wherein the surface is hydrophobic (Column 9, lines 50-56 and Column 22, lines 8-20).

Regarding Claim 13, Winkler et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 23, lines 13-18).

Regarding Claim 14, Winkler et al disclose the substrate wherein the DNA sequences are covalently bound (Column 10, lines 43-47).

Regarding Claim 15, Winkler et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 5, lines 42-47 and Column 10, lines 43-47).

Regarding Claim 17, Winkler et al disclose the substrate wherein the sequences are DNA sequences (Column 6, lines 18-22) that are comprised of nucleotides A, T, G, C. The claims are drawn to fragments of genomic DNA, which encompasses combinations of as few as two A, T, G, C. Because the claims are drawn to as few as two A, T, G and/or C and because Winkler et al teach 50mers of A, T, G and/or C. Winkler is deemed to teach the sequences as claimed.

Regarding Claim 18, Winkler et al disclose the substrate has at least 2500 or more regions i.e. 10,000/cm^2 (Column 18, lines 47-50).

Regarding Claim 19, Winkler et al disclose the substrate has at least 10,000 regions (Column 18, lines 47-50).

Regarding Claim 21, Winkler et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length (Column 17, lines 49-57 and Column 18, lines 47-50). Winkler et al does not teach the method steps recited in the claim. However, the method steps do not result in any structural or compositional difference over the substrate of Winkler.

Furthermore, as cited above, the courts have stated that the process of making a product does not distinguish the product over the prior art.

Regarding Claim 22, Winkler et al disclose the substrate wherein density is at least 10,000 regions/cm^2 (Column 18, lines 47-50).

Regarding Claim 23, Winkler et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm^2 (Column 18, lines 47-50)

Regarding Claim 24 Winkler et al disclose the substrate wherein the substrate is glass (Column 14, lines 45-46).

Regarding Claim 25 Winkler et al disclose the substrate wherein the substrate is non-porous i.e. glass (Column 14, lines 45-46).

Regarding Claim 26, Winkler et al disclose the substrate wherein the surface is hydrophobic (Column 9, lines 50-56 and Column 22, lines 8-20).

Regarding Claim 27, Winkler et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 23, lines 13-18).

Regarding Claim 29, Winkler et al disclose the substrate wherein the DNA sequences are covalently bound (Column 10, lines 43-47).

Regarding Claim 30, Winkler et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 5, lines 42-47 and Column 10, lines 43-47).

Regarding Claim 31, Winkler et al disclose the substrate wherein the sequences are DNA sequences (Column 6, lines 18-22), which are, comprised of nucleotides A, T, G, C. The claims are drawn to fragments of genomic DNA that encompasses combinations of as few as two A, T, G, C. Because the claims are drawn to as few as two A, T, G and/or C and because Winkler et al teach 50mers of A, T, G and/or C. Winkler is deemed to teach the sequences as claimed.

Regarding Claim 32, Winkler et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm^2 (Column 18, lines 47-50)

Regarding Claim 33, Winkler et al disclose the substrate wherein density is at least 10,000 regions/cm^2 (Column 18, lines 47-50).

Regarding Claim 34, Winkler et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm^2 wherein the DNA sequences are about 50 subunits in length (Column 17, lines 49-57 and Column 18, lines 47-50). Winkler et al does not teach the method steps recited in the claim. However, the claimed selective hybridization is a recitation of intended use and, as cited above, the courts have stated that a recitation of intended use not distinguish a device over the prior art. Therefore, the detection does not further define the substrate.

Regarding Claim 35, Winkler et al disclose the substrate of Claim 34 but do not teach the detection as recited in the claim. However, the claimed detection is a recitation of intended use and the courts have stated that a recitation of intended use not distinguish a device over the prior art. Therefore, the detection does not further define the substrate of Claim 34.

Regarding Claim 38, Winkler et al disclose the substrate wherein the DNA is used to detect distinct sequences wherein relative binding is analyzed (e.g. Column 7, line 43-Column 8, line 7).

Regarding Claim 39, Winkler et al disclose the substrate wherein the DNA is used to detect distinct sequences wherein relative binding is analyzed (e.g. Column 7, line 43-Column 8, line 7).

Regarding Claim 40, Winkler et al disclose the substrate wherein the regions are of a density between about 62,500 and 625 regions/cm^2 (e.g. 10,000 regions, Column 18, lines 43-50).

Response to Arguments

8. Applicant asserts that the Winkler et al reference does not provide any enabling data that arrays of polymers could be produced. Applicant argues that "the stated of the art at the time of the filing of Winkler et al (i.e., Nov, 1992) suggests that numerous inherent drawbacks of in situ synthesis including low coupling efficiency and premature truncation of a polymer limit the length of the synthesized polymers and their homogeneity." The arguments have been considered but are not found persuasive. As stated above, Applicant has not provided any factual evidence of the asserted inability. Therefore, the assertion is deemed unsupported arguments of counsel. This is not to be considered an invitation for Applicant to submit a Declaration because a Declaration submitted after Final Action would not be deemed timely.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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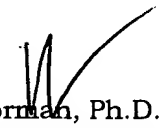

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 17, 2006